

Blood Cell Storage, Inc. 4203 23rd Ave W. Seattle WA, 98199 USA

Certificate of Compliance

Date of Manufacture: 17 June 2022

Product Name: BCSI pH SAFE Reader (pH1000TM)

Part Number: 400001

Lot Number: 2206010[†]

BCSI pH1000 Serial Number: BCS0809P0110

BCSI pH1000 QC Standard Serial Number: B397

Serial Number	Fr	Fp	Rp
B397	1602	2574	1.729



B3971602257417290141

NOTE: These criteria are specific for the pH1000 paired with the QC Standard as stated above. The Fr and Fp values must be within 5% of the listed value. The Rp value must be within 1% of the listed value.

One (1) year from date of barcode scan

Quality

ISO 13485

ISO 9001

USER: Record the expiry date on the SQC label.

BCSI certifies that the above referenced product:

- Was tested by BCSI whose Quality Management System is approve by an accredited registering body to the appropriate ISO 13485:2016 Medical Devices Quality Systems Standard and ISO 9001:2015 Quality Systems Standard.
- Was tested in accordance with applicable BCSI Standard Procedures.
- Was tested and complies with visual and performance specifications as specified in the product specification.

Steve Geelhood

Date

Business Director 400001-07